

**§ 172.375 Potassium iodide.**

The food additive potassium iodide may be safely used in accordance with the following prescribed conditions:

(a) Potassium iodide may be safely added to a food as a source of the essential mineral iodine, provided the maximum intake of the food as may be consumed during a period of one day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive so as to provide a total amount of iodine in excess of 225 micrograms for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 45 micrograms for infants, 105 micrograms for children under 4 years of age, 225 micrograms for adults and children 4 or more years of age, and 300 micrograms for pregnant or lactating women.

(b) To assure safe use of the additive, in addition to the other information required by the Act, the label of the additive shall bear:

- (1) The name of the additive.
- (2) A statement of the concentration of the additive in any mixture.

**§ 172.380 Vitamin D<sub>3</sub>.**

The food additive may be used safely in foods as a nutrient supplement defined under § 170.3(o)(20) of this chapter in accordance with the following prescribed conditions:

(a) Vitamin D<sub>3</sub>, also known as cholecalciferol, is the chemical 9,10-seco(5Z,7E)-5,7,10(19)-cholestatrien-3-ol. Vitamin D<sub>3</sub> occurs in and is isolated from fish liver oils. It also is manufactured by ultraviolet irradiation of 7-dehydrocholesterol produced from cholesterol and is purified by crystallization.

(b) Vitamin D<sub>3</sub> meets the specifications of the *Food Chemicals Codex*, 4<sup>th</sup> ed. (1996), p. 434, which is incorporated by reference. The Director of the Office of the Federal Register approves this incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. You may obtain copies from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418 (Internet address <http://www.nap.edu>). Copies may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and

Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) Vitamin D<sub>3</sub> may be added, at levels not to exceed 100 International Units (IU) per serving, to 100 percent fruit juices, as defined under § 170.3(n)(35) of this chapter, excluding fruit juices that are specially formulated or processed for infants, that are fortified with greater than 33 percent of the Recommended Daily Intake (RDI) of calcium per Reference Amount Customarily Consumed (RACC).

(d) Vitamin D<sub>3</sub> may be added, at levels not to exceed 100 IU per serving, to fruit drinks, as defined under § 170.3(n)(35) of this chapter, excluding fruit drinks that are specially formulated or processed for infants, that are fortified with greater than 10 percent of the RDI of calcium per RACC.

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**§ 172.385 Whole fish protein concentrate.**

The food additive whole fish protein concentrate may be safely used as a food supplement in accordance with the following prescribed conditions:

(a) The additive is derived from whole, wholesome hake and hake-like fish, herring of the genera *Clupea*, menhaden, and anchovy of the species *Engraulis mordax*, handled expeditiously and under sanitary conditions in accordance with good manufacturing practices recognized as proper for fish that are used in other forms for human food.

(b) The additive consists essentially of a dried fish protein processed from the whole fish without removal of heads, fins, tails, viscera, or intestinal contents. It is prepared by solvent extraction of fat and moisture with isopropyl alcohol or with ethylene dichloride followed by isopropyl alcohol, except that the additive derived from herring, menhaden and anchovy is prepared by solvent extraction with isopropyl alcohol alone. Solvent residues are reduced by conventional heat drying and/or microwave radiation and there is a partial removal of bone.

(c) The food additive meets the following specifications: